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|---|---|--|---------------------|------------------|--|
| APPLICATION NO.                         | FILING DATE   | FIRST NAMED INVENTOR                     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
| 10/519,621                              | 12/28/2004  | Luc Desnoyers                            | P1918R1             | 9135             |  |
| 9157 7590 07/25/2007<br>GENENTECH, INC. |   | EXAMINER                                 |                     |                  |  |
| l DNA WAY                               | l DNA WAY<br>SOUTH SAN FRANCISCO, CA 94080  |  |                     | GAMETT, DANIEL C |  |
| S. SOOTH SAIN F                         | RANCISCO, CA 94080  |  | ART UNIT            | PAPER NUMBER     |  |
|   |   |  | 1647                | <u> </u>         |  |
|   |   |  | MAIL DATE           | DELIVERY MODE    |  |
|   |   |  | 07/25/2007          | PAPER            |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  |   | Application No.  | Applicant(s)                       |  |  |  |
|--|---|--|------------------------------------|--|--|--|
| Office Action Summary  |   | 10/519,621   | DESNOYERS ET AL.                   |  |  |  |
|  |   | Examiner   | Art Unit                           |  |  |  |
|  |   | Daniel C. Gamett, PhD  | 1647                               |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |  |                                    |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |  |                                    |  |  |  |
| Status   |   |  |                                    |  |  |  |
| 1)   | Responsive to communication(s) filed on 29 M  | ay 2007.   | •                                  |  |  |  |
| 2a) <u></u> □  | This action is <b>FINAL</b> . 2b)⊠ This   | action is non-final.   |                                    |  |  |  |
| 3) 🗌   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |  |                                    |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |  |                                    |  |  |  |
| Dispositi  | on of Claims  |  |                                    |  |  |  |
| 5)□<br>6)⊠<br>7)□  | Claim(s) 9 and 11-14 is/are pending in the app 4a) Of the above claim(s) is/are withdray Claim(s) is/are allowed. Claim(s) 9 and 11-14 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or   | vn from consideration.   |                                    |  |  |  |
| Application Papers   |   |  |                                    |  |  |  |
|  |   |  |                                    |  |  |  |
| <ul> <li>9)  The specification is objected to by the Examiner.</li> <li>10)  The drawing(s) filed on 28 December 2004 is/are: a)  accepted or b)  objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>  |   |  |                                    |  |  |  |
| Priority u   | nder 35 U.S.C. § 119  |  |                                    |  |  |  |
| a)[  | Acknowledgment is made of a claim for foreign  All b) Some * c) None of:  1 Certified copies of the priority documents  2 Certified copies of the priority documents  3 Copies of the certified copies of the priority documents  application from the International Bureau  see the attached detailed Office action for a list | s have been received.<br>s have been received in Applicati<br>ity documents have been receive<br>I (PCT Rule 17.2(a)). | on No<br>ed in this National Stage |  |  |  |
| Attachment   | t(s)  |  |                                    |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |   |  |                                    |  |  |  |
| 3) 🔯 Inform  | e of Draftsperson's Patent Drawing Review (PTO-948)<br>nation Disclosure Statement(s) (PTO/SB/08)<br>r No(s)/Mail Date <u>02/27/2006 10/17/2006</u> .   | Paper No(s)/Mail Do 5) Notice of Informal F 6) Other:  |                                    |  |  |  |

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## **DETAILED ACTION**

1. Applicant's election without traverse of Group I (claims 1, 7, 9, 13, and 14 in part, and claims 2-4, 11, 12, and 22-29) drawn to anti-WISP-1 antibodies and a method of inhibiting or neutralizing WISP-1 induction or secretion of HAS2, HA, CD44, or RHAMM in mammalian cells, comprising exposing said mammalian cells to a WISP-1 antibody in the reply filed on 05/29/2007 is acknowledged.

2. The amendments of 05/29/2007 have been entered in full. Claims 1-8, 10, and 15-30 are cancelled. Claims 9 and 11-14 are under examination.

# Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 4. Claim 9 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9921998 A1, published May 6, 1999 (of record).
- 5. The instant claims are drawn to a method of inhibiting or neutralizing WISP-1 induction or secretion of HAS2, HA, CD44, or RHAMM in mammalian cells, comprising exposing said mammalian cells to a WISP-1 antibody. Dependent claims recite that the anti-WISP-1 antibody binds to native human WISP-1 comprising amino acids 23-367 of FIGS. 9A-9C (SEQ ID NO: 1) (claim 11), is a chimeric, humanized or human antibody (claim 12), and that the cells are cancer

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cells (claim 13), specifically colon or colorectal cancer cells, breast cancer cells, lung cancer cells or brain cancer cells (claim 14). WISP-1 is identified in 9921998 as SEQ ID NO: 4, which is 100% identical to SEQ ID NO:1 recited in instant claim 11 (see alignment in Appendix A). WO 9921998 teaches antagonist antibodies to WISP-1, including chimeric, humanized, or human antibodies (page 12, lines 1-5; page 75, lines 1-4). WO 9921998 teaches the use of such antibodies for treatment of cancers wherein WISP-1 is expressed, including colon, lung, breast, and other cancers (page 51, lines 4-15; paragraph bridging pages 74-75). Treatment of colon cancer is taught as a preferred embodiment at page 12, lines 6-9. WO 9921998 exemplifies a method comprising exposing mammalian breast cancer cells to an effective amount of a WISP-1 antagonist antibody at least in Example 14 (pages 73-74). Therefore, WO 9921998 teaches exposure of the same cell populations to the same reagents that are recited in the instant claims, which necessarily would result in all of the same outcomes.

### Conclusion

### 6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571 272 0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/DAVID ROMEO/ PRIMARY EXAMINER ART UNIT 1647

DCG Art Unit 1647 20 July 2007

#### APPENDIX A

```
RESULT 1
AAY17641
     AAY17641 standard; protein; 367 AA.
XX
AC
     AAY17641;
XX
DΤ
     06-AUG-1999 (first entry)
XX
     Human WISP-1 protein SEQ ID NO:4.
DΕ
XX
     WNT-1 induced secreted protein; WISP-1; WISP-2; WISP-3; CTGF; tumour;
KW
     connective tissue growth factor; cancer; melanoma; arteriosclerosis;
KW
     leukaemia; lymphoid malignancy; haematopoiesis-related disorder;
KW
     tissue-growth disorder; skin disorder; desmoplasia; fibrotic lesion;
KW
KW
     kidney disorder; bone-related disorder; osteoporosis; trauma; burn;
     connective tissue disorder; catabolic state; inflammation;
KW
ΚW
     testicular-related disorder; angiogenesis; immunological disorder.
XX
OS
     Homo sapiens.
XX
     WO9921998-A1.
PΝ
XX
     06-MAY-1999.
₽D
XX
     29-OCT-1998; 98WO-US022991.
PF
XX
PR
     29-OCT-1997;
                    97US-0063704P.
PR
     03-FEB-1998;
                    98US-0073612P.
PR
     14-APR-1998;
                    98US-0081695P.
XX
PΑ
     (GETH ) GENENTECH INC.
XX
PΙ
     Botstein DA, Cohen RL, Gurney AL, Hillan K, Lawrence DA;
     Levine AJ, Pennica D, Roy MA, Goddard A, Wood WI;
PΙ
XX
     WPI; 1999-337420/28.
DR
     N-PSDB; AAX76482.
DR
XX
     New isolated Wnt-1 induced secreted polypeptides, WISP-1, 2 and 3.
PT
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```
XX
PS
     Claim 4; Page 163-164; 284pp; English.
XX
CC
     The present invention describes Wnt-1 induced secreted polypeptides, WISP
     -1, 2 and 3. The novel WISP polypeptides, designated WISP-1, WISP-2 and
CĊ
     WISP-3 have homology to connective tissue growth factor (CTGF). Products
CC
CC
     from the present invention can be used to treat WISP-related disorders
CC
     such as breast, ovarian, and colon cancer or melanoma. The products can
     be used to treat arteriosclerosis. The products can also be used to treat
CC
     other diseases e.g. benign and malignant tumours, leukaemia and lymphoid
CC
CC
     malignancies, neuronal, glial, astrocytal, hypothalamic and other
     glandular, macrophagal, epithelial, stromal, and blastocoelic disorders,
CC
CC
     haematopoiesis-related disorders, tissue-growth disorders, skin
CC
     disorders, desmoplasia, fibrotic lesions, kidney disorders, bone-related
     disorders such as osteoporosis, trauma such as burns, incisions, and
CC
CC
     other wounds, connective tissue disorders, catabolic states, testicular-
CC
     related disorders, and inflammatory, angiogenic and immunologic disorders
CC
     including arteriosclerosis. The products can also be used for detection
CC
     and diagnosis especially of individuals with neoplastic cell growth or
CC
     proliferation. The products can be used in the production of transgenic
CC
     or knock-out animals. Antibodies can be used to induce death in WISP-1, 2
CC
     or 3 overexpressing cells
XX
SO
     Sequence 367 AA;
                       100.0%; Score 2099; DB 2;
  Query Match
                                                 Length 367;
                       100.0%; Pred. No. 3e-145;
  Best Local Similarity
  Matches 367; Conservative
                             0; Mismatches
                                                 Indels
                                                             Gaps
0;
           1 MRWFLPWTLAAVTAAAASTVLATALSPAPTTMDFTPAPLEDTSSRPOFCKWPCECPPSPP 60
Qy
             1 MRWFLPWTLAAVTAAAASTVLATALSPAPTTMDFTPAPLEDTSSRPQFCKWPCECPPSPP 60
Db
          61 RCPLGVSLITDGCECCKMCAQQLGDNCTEAAICDPHRGLYCDYSGDRPRYAIGVCAQVVG 120
Qу
             Db
          61 RCPLGVSLITDGCECCKMCAQQLGDNCTEAAICDPHRGLYCDYSGDRPRYAIGVCAQVVG 120
Qу
         121 VGCVLDGVRYNNGQSFQPNCKYNCTCIDGAVGCTPLCLRVRPPRLWCPHPRRVSIPGHCC 180
             Db.
        121 VGCVLDGVRYNNGQSFQPNCKYNCTCIDGAVGCTPLCLRVRPPRLWCPHPRRVSIPGHCC 180
         181 EOWVCEDDAKRPRKTAPRDTGAFDAVGEVEAWHRNCIAYTSPWSPCSTSCGLGVSTRISN 240
· Qy
             Db
         181 EQWVCEDDAKRPRKTAPRDTGAFDAVGEVEAWHRNCIAYTSPWSPCSTSCGLGVSTRISN 240
         241 VNAQCWPEQESRLCNLRPCDVDIHTLIKAGKKCLAVYQPEASMNFTLAGCISTRSYQPKY 300
Qу
             Db
         241 VNAQCWPEQESRLCNLRPCDVDIHTLIKAGKKCLAVYQPEASMNFTLAGCISTRSYQPKY 300
         301 CGVCMDNRCCIPYKSKTIDVSFQCPDGLGFSRQVLWINACFCNLSCRNPNDIFADLESYP 360
Qу
             Db
         301 CGVCMDNRCCIPYKSKTIDVSFQCPDGLGFSRQVLWINACFCNLSCRNPNDIFADLESYP 360
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Qу 361 DFSEIAN 367

Db

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